# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

VIACELL INC., CRYO-CELL INTERNATIONAL, INC. and CORCELL, INC.	) ) )
Plaintiffs,	) Civil Action No. 04-1335-GMS )
v.	) ) JURY TRIAL DEMANDED
PHARMASTEM THERAPEUTICS, INC.,	)
Defendant.	Ś

### AMENDED COMPLAINT

### INTRODUCTION

This case involves an unlawful, anticompetitive, and deceptive campaign by defendant PharmaStem Therapeutics, Inc. ("PharmaStem") to unreasonably restrain trade in and to monopolize the market for private cord blood banking in the United States. Through a series of wrongful and exclusionary agreements and actions, PharmaStem is seeking to coerce a boycott by health care providers of plaintiffs ViaCell Inc. ("ViaCell"), Cryo-Cell International, Inc. ("Cryo-Cell"), CorCell, Inc. ("CorCell") and other providers of private cord blood banking services. PharmaStem's goal is to force private cord blood banks to accept unnecessary and overbroad licenses to certain PharmaStem patents, which would require the companies to pay royalties to PharmaStem even for non-infringing conduct. Unless stopped, the inevitable result of PharmaStem's conduct is that consumers – the families of newborn infants – will be improperly required to pay higher prices for private cord blood banking services. Further, many families are being, and will be, deprived of the once-in-a-lifetime opportunity to preserve cord blood as a result of PharmaStem's actions.

- 2. PharmaStem's wrongful and anticompetitive campaign involves two steps. First, PharmaStem has repeatedly and improperly asserted, and continues to assert, that any collection of cord blood by obstetricians or hospitals infringes its patents. That blanket assertion of infringement is demonstrably false, misleading, and objectively unreasonable, as PharmaStem itself knows. PharmaStem's patents are subject to significant limits. As a result, obstetricians and hospitals simply cannot incur liability under PharmaStem's patents merely by collecting umbilical cord blood. Nonetheless, PharmaStem has sued numerous hospital and doctors (not to mention private cord blood banks) for patent infringement. In addition, PharmaStem has repeatedly made false and misleading public statements about its patents. This Court has already ruled that statements by PharmaStem in this regard were false and misleading, and enjoined PharmaStem from making false and misleading statements to obstetricians in the future. In defiance of the Court's order, PharmaStem has sent letters to literally tens of thousands of doctors that contain inaccurate, false, and misleading assertions of patent infringement against the doctors related to private cord blood banking. This conduct itself is wrongful, exclusionary, and deceptive, and is part of PharmaStem's overall anticompetitive scheme.
- 3. Second, after making its unsupportable infringement allegations and public misstatements, PharmaStem presented doctors or hospitals with what is called an "Amnesty Agreement." In these wrongful agreements, PharmaStem agrees to drop all charges and/or not to file suit if the doctor or hospital agrees to a complete boycott of any private cord blood bank that has not signed one of PharmaStem's wrongful licenses. The terms of these "Amnesty Agreements," and the boycotts they impose, are far broader than any legitimate right to exclude PharmaStem may have from its patents. For example, the "Amnesty Agreements" purport to

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prohibit the mere collection of blood, but no claim of any PharmaStem patent is directly or indirectly infringed by mere collection. Thus, the "Amnesty Agreements" would prohibit doctors and hospitals from engaging in a broad array of non-infringing conduct. PharmaStem is actively working to execute such agreements with literally tens of thousands of doctors. The "Amnesty Agreements" are wrongful and anticompetitive, both on their own and as part of PharmaStem's overall anticompetitive scheme.

- PharmaStem has wrongfully coerced numerous hospitals and physicians into 4. signing "Amnesty Agreements" and boycotting private cord blood banks that have refused to enter into PharmaStem's wrongful licenses. On information and belief, additional doctors and/or hospitals are signing and will sign PharmaStem's wrongful "Amnesty Agreements" rather than subject themselves to the costs and burdens of PharmaStem's wrongful tactics. The doctors are susceptible to PharmaStem's pressure tactics, because they generally have no vested interest in working with any particular blood bank. Some hospitals and obstetricians have simply ordered their staffs not to collect cord blood at all, regardless of which cord blood banks will be used, to avoid the risk of litigation with PharmaStem. This is adversely affecting patients' ability to collect and store cord blood – an opportunity that, once lost, can never be recovered.
- 5. ViaCell, Cryo-Cell and CorCell are private cord blood banks that provide a range of services to customers. ViaCell, Cryo-Cell and CorCell have successfully defended against patent infringement claims by PharmaStem. This Court recently ruled that ViaCell, Cryo-Cell and CorCell do not infringe one of PharmaStem's patents (the '553 patent) as a matter of law, and it granted a new trial on infringement with respect to another of PharmaStem's patents (the '681 patent), while affirming the limitations on the '681 patent.

PharmaStem's anticompetitive conduct directly targets ViaCell, Cryo-Cell and CorCell.

Among other things, PharmaStem explicitly lists ViaCell, Cryo-Cell and CorCell in its

"Amnesty Agreements" as entities to be boycotted.

- 6. In the past few weeks, obstetricians and hospitals have contacted ViaCell, Cryo-Cell and CorCell to state that they will no longer collect blood for patients to be stored with ViaCell, Cryo-Cell and CorCell. These effects are already irreparably harming the business of ViaCell, Cryo-Cell and CorCell. If PharmaStem's conduct continues unchecked, the situation threatens to get worse.
- 7. PharmaStem's conduct is having a market-wide impact. At least 16 private cord blood banks allegedly have already signed license agreements with PharmaStem. As a consequence, companies have raised their prices because of the royalties they must pay to PharmaStem under the wrongful licenses. There are only four remaining private banks that have not succumbed to PharmaStem's tactics, and PharmaStem continues to target them aggressively with its unlawful conduct. Thus, consumers of private cord blood banking services are currently, or soon likely will be, paying more for those services than they would pay in the absence of PharmaStem's wrongful conduct.
- 8. ViaCell, Cryo-Cell and CorCell bring this action under the federal antitrust laws, 15 U.S.C. § 1 et seq., the federal Lanham Act, 15 U.S.C. § 1125 et seq., and various state laws. PharmaStem's conduct threatens to unreasonably restrain trade, and threatens to lead to a wrongful monopoly, in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2, unless PharmaStem is enjoined. ViaCell, Cryo-Cell and CorCell request that the Court grant a preliminary and a permanent injunction enjoining PharmaStem's ongoing anticompetitive conduct, including but not limited to preventing the enforcement of the so-called "Amnesty

Agreements," preventing PharmaStem from entering into any further such agreements, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and voiding the agreements already signed. ViaCell, Cryo-Cell and CorCell also seek damages for the losses they have suffered from PharmaStem's wrongful, anticompetitive, and deceptive conduct in violation of Sections 1 and 2 of the Sherman Act under Section 4 of the Clayton Act, 15 U.S.C. § 15, in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and in violation of state law.

#### **PARTIES**

- 9. Plaintiff ViaCell, Inc. ("ViaCell") is a Delaware corporation with a principal place of business located 245 First Street, Cambridge, Massachusetts 02142.
- ViaCell, through its subsidiary ViaCord, provides private blood banking services for families that wish to preserve umbilical cord blood units ("cord blood") following the birth of a child. If a family elects to do so, cord blood is collected at the time of birth by physicians. The blood is then transported to ViaCell for testing and storage. Because cord blood generally contains stem cells, cord blood can potentially be useful for treating certain diseases if they arise in the future. Different cord blood units contain differing amounts of stem cells. Depending on the amount of stem cells in a particular unit, it may or may not prove therapeutically useful.
- 11. All of ViaCell's cord blood banking business is conducted through its facilities in Massachusetts. ViaCell's call center for cord blood banking is located in Massachusetts. Agreements between ViaCell and customers relating to cord blood banking are executed in Massachusetts, and those agreements contain a choice-of-law provision specifying that Massachusetts law governs.
- 12. Plaintiff Cryo-Cell is a Delaware corporation with its principal place of business at 3165 N. McMullen Booth Road, Clearwater, Florida 33761.

- Plaintiff CorCell is a Delaware corporation with its principal place of business 13. located at 1411 Walnut Street, Philadelphia, Pennsylvania 19103. CorCell provides private blood banking services for families that wish to preserve umbilical cord blood units following the birth of a child.
- Defendant PharmaStem Therapeutics, Inc. ("PharmaStem") is a Delaware 14. corporation with a principal place of business located in Larchmont, New York 10538.

## JURISDICTION AND VENUE

- 15. The Court has jurisdiction over ViaCell's federal claims pursuant to 28 U.S.C. § 1331, 15 U.S.C. § 1 et seq., 15 U.S.C. § 1125 et seq., and of ViaCell's state-law claims pursuant to 28 U.S.C. § 1367.
- Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 15 16. U.S.C. §§ 15 and 22 as a district in which the defendant resides, may be found and/or transacts business.

### PHARMASTEM'S PATENTS AND THE PRIOR COMPETITOR LITIGATION

- 17. On information and belief, PharmaStem is the assignee of five patents relating to cord blood banking (collectively "PharmaStem's patents"). Those patents are U.S. Patent No. 5,004,681 (the "'681 Patent"), U.S. Patent No. 5,192,553 (the "'553 Patent"), U.S. Patent No. 6,461,645 (the "'645 Patent"), U.S. Patent No. 6,569,427 (the "'427 Patent"), and U.S. Patent No. 6,605, 275 (the "'275 Patent").
- 18. Individually and collectively, PharmaStem's patents do not apply to the preservation of all cord blood or to all actions taken in connection with the collection and preservation of cord blood. Moreover, there is no objectively reasonable, good faith interpretation of PharmaStem's patents which suggests that those patents, individually and collectively, cover the preservation of all cord blood or all actions taken in connection with the

collection and preservation of cord blood. Thus, families, health care providers and blood banks can engage in numerous actions with regard to cord blood banking without infringing PharmaStem's patents. For example, no claim of any PharmaStem patent covers the mere collection of cord blood.

- Hospitals and/or physicians that collect cord blood, which a patient then 19. provides to a private bank, do not infringe PharmaStem's patents. There is no direct infringement, because doctors and/or hospitals do not practice all of the claimed elements. There is no contributory infringement, because (among other things) neither hospitals nor doctors sell or offer to sell the cord blood. There is no inducement to infringe, because that requires evidence that the doctors or hospitals actively and knowingly aided and abetted another's direct infringement.
- 20. The context in which PharmaStem's current anticompetitive campaign must be understood includes a recent lawsuit PharmaStem commenced against all of the principal players in the private cord blood banking market. On or about February 22, 2002, PharmaStem filed a lawsuit against ViaCell, Cryo-Cell and CorCell and five other private cord blood banks, alleging infringement of the '553 Patent and the '681 Patent. PharmaStem Therapeutics, Inc. v. ViaCell, Inc. et al., Civil Action No. 02-148-GMS (D.Del.) (Sleet, J.) (the "Competitor Litigation").
- 21. The private cord blood bank defendants in the Competitor Litigation denied liability and defended against PharmaStem's allegations on the grounds, inter alia, of noninfringement and that the patents were invalid and unenforceable.
- 22. On or about October 29, 2003, the jury in the Competitor Litigation returned a verdict in PharmaStem's favor.

- 23. Following the jury verdict, the parties submitted several post-trial motions. The private cord blood bank defendants moved for, among other things, the entry of judgment of non-infringement as a matter of law or, in the alternative, a new trial.
- 24. The Court in the Competitor Litigation issued a Memorandum and Order dated September 15, 2004 on the parties' post-trial motions. The Court granted judgment as a matter of law that the private cord blood banks do not infringe the '553 Patent, and granted a new trial on infringement of the '681 Patent. The Court also denied PharmaStem's motions, including its motion for entry of a permanent injunction.

## PHARMASTEM'S ANTICOMPETITIVE CAMPAIGN TO COERCE A BOYCOTT OF PRIVATE CORD BLOOD BANKS

- 25. Prior to the Court's September 15 Order in the Competitor Litigation, PharmaStem embarked on its improper and anticompetitive scheme targeting hospitals and obstetricians. On information and belief, PharmaStem's purpose and intent was and is to choke off the supply of cord blood to the private cord blood banks that have resisted PharmaStem's efforts to force them to accept a wrongful and overbroad license. Through a variety of means, PharmaStem is bullying health care providers into a boycott of ViaCell, Cryo-Cell and CorCell. In this manner, PharmaStern is attempting to achieve through improper, unfair, deceptive, and anticompetitive practices the goal it is not entitled to achieve under its patents - forcing all private blood banks to accept licenses and pay royalties to PharmaStem in connection with all of their cord blood banking activities, whether or not those activities actually infringe PharmaStem's patents.
- 26. On or about June 1, 2004, while the post-trial motions in the Competitor Litigation were still pending, PharmaStem began sending to obstetricians, and perhaps to others, letters substantially in the form attached hereto as Exhibit 1 ("the PharmaStem June

- letter"). The PharmaStem June letter contained numerous false and misleading statements concerning the Court's rulings to date, as well as the doctors' potential liability for infringement of PharmaStem's patents. The letter was sent to over 25,000 obstetricians.
- By Order dated July 2, 2004, this Court (Sleet, J.) found that the PharmaStem 27. June letter contained false and misleading statements. The Court also granted an injunction against further false or misleading communications directed to obstetricians. A copy of the Court's Order is attached hereto as Exhibit 2. In particular, Judge Sleet found, in pertinent part, that:
  - PharmaStem's June 1, 2004 letter to Obstetricians (the "PharmaStem Letter") contains false and misleading statements concerning this Court's rulings to date. In particular, the Court finds the following statements in this PharmaStem Letter false and misleading:
    - "Patent infringement occurs when a person or institute practices all or part of a patented process." The Court finds this statement is misleading because it is black letter law that in order to prove contributory infringement of a method patent, the entire By suggesting that patented process must be performed. infringement would occur when only part of a process in performed, the letter is misleading.
    - "In the case of umbilical cord blood collection by an obstetrician, the Court ruled that infringement occurs even if the cryopreservation and storage is performed by a third party." The Court finds this statement misleading for at least the following reasons. First, the sentence states that "the Court ruled" with respect to the "case" of "umbilical cord blood collection by an Obstetrician." This Court never made any rulings regarding conduct by obstetricians. There were no such allegations advanced in the trial of this matter. Second, the sentence leaves out several important elements that must be proved to show contributory infringement. The missing elements include:
      - that there must be a sale or offer to sell, by the party that is accused of contributory infringement,
      - that the party accused of contributory infringement must be "acting in concert or working together"

each and every element of the patented process, and

3. that, under §271(c), a sale of a service, as opposed to a sale of a tangible physical object, is not sufficient to satisfy the requirements of the contributory infringement statute.

The Court finds that without these elements, the statement is misleading.

- 28. PharmaStem followed its June letter with a second wave of lawsuits, in each of which PharmaStem sued a private cord blood bank and one or more health care providers (individual physicians), group medical practices and a hospital, for patent infringement. PharmaStem filed five such lawsuits, in locations throughout the country (the "Provider Lawsuits"). Those lawsuit are:
  - (a) PharmaStem Therapeutics, Inc. v. Corcell, Inc., Molly McBride, M.D., and Carlo M. Croce, M.D., C.A. No. 04-CV-3561 (E.D. Pa.).
  - (b) PharmaStem Therapeutics, Inc. v. Cord Blood Registry, Inc. and Sutter Health, Inc., C.A. No. 04-3072 (PVT) (N.D. Cal.).
  - (c) PharmaStem Therapeutics, Inc. v. Cryo-Cell International, Inc. and Bruce Zafran, M.D., C.A. No. 8:04-CV-1740-T-30TGW (M.D. Fla.).
  - (d) PharmaStem Therapeutics, Inc. v. Curesource, Inc., Monica Aszlerbaum,
    Andrew Cassidenti, Eunice U. Lee, Carla Wells, Anita York, Eliot Romero, Kathy
    Anderson, Nasrin Farbakhsh, Bruce A. Hagadorn, Rahasree T. Seshadri, Arthur
    Goldstein, and Charles W. Moniak, SACV04-921 (GLT) (C.D.Cal.).
  - (e) PharmaStem Therapeutics, Inc. v. ViaCell, Inc., Obstetrical and Gynecological Associates, P.A., Fempartners, Inc., and Caritas St. Elizabeth's Medical Center of Boston, Inc., C.A. No. 04-11673 (RWZ) (D. Mass.).

- 29. On information and belief, PharmaStem deliberately filed the Provider Lawsuits in locations throughout the country to maximize the effect of those lawsuits in intimidating health care providers - including those not sued by PharmaStem - with the threat of patent litigation.
- 30. In each of the Provider Lawsuits, PharmaStem made a boilerplate allegation of infringement of the '427 patent against both the defendant private cord blood bank and at least one health care provider.
- 31. On August 2, 2004, after PharmaStem filed the Provider Lawsuits, PharmaStem issued a press release ("August 2 Press Release"), a copy of which is attached hereto as Exhibit 3. The August 2 Press Release contained statements similar to those in the PharmaStem June Letter which the Court had found to be false and misleading. PharmaStem's press release was at odds with the July 2 injunction. PharmaStem caused copies of the Press Release to be mailed to thousands of obstetricians.
- 32. Shortly after initiating one of the Provider Lawsuits in the Central District of California against CureSource, Inc., and twelve physicians, PharmaStem sent a letter to the defendant physicians, offering to "settle" with them by agreeing not to enforce any of PharmaStem's five patents against them, provided the doctors would agree (1) not to collect cord blood or provide any service "in connection with" any of the private cord blood banks not licensed by PharmaStem, and (2) agree not to market or offer any service of the defendant cord blood banking companies. A copy of one of these letters, dated August 18, 2004, with the proposed agreement, is attached hereto as Exhibit 4.
- 33. On or about August 20, 2004, PharmaStem began to send thousands of letters, again containing the same type of misleading statements, to physicians whom it had not sued.

These letters informed the recipients of PharmaStem's "recent lawsuits filed across the United States against obstetricians who continue to collect cord blood or market services, including distribution of literature, for . . . . ViaCord, CBR (Cord Blood Registry), Cryo-Cell, Corcell and CureSource." PharmaStem also asserted:

"It is PharmaStem's position, as asserted in the recent lawsuits, that obstetricians are liable for patent infringement if they collect cord blood or market services for unlicensed cord blood banks.

In an effort to avoid legal action from PharmaStem relating to its patents, please review and sign the attached Amnesty Agreement." (emphasis added)

A copy of one of these letters is attached hereto as Exhibit 5.

- Attached to these letters was a so-called "Amnesty Agreement," which 34. PharmaStem insisted that the doctors sign to avoid legal action by PharmaStem. As in the case of the August 18, 2004 letter, the Amnesty Agreement required the physicians to agree "not to collect cord blood or market or offer the service of cord blood collection in connection with the unlicensed cord blood banks listed below." A copy of an "Amnesty Agreement" is attached hereto as Exhibit 6. None of PharmaStem's patents could support such a broad and sweeping restriction on the activities of doctors.
- 35. On or about September 14, 2004, PharmaStem sent another letter to obstetricians. This letter purported to be a settlement communication, but actually was a thinlyveiled attempt to bully and threaten obstetricians into joining PharmaStem's boycott. In this letter, PharmaStem threatened the doctors it had sued with "considerable time, expense, intrusion, and other inevitable tangible and intangible costs" if the doctors refused to settle. As with PharmaStem's other letters, this letter conditioned settlement on the doctors' agreeing to the same overbroad requirement "to collect only for one of the many cord blood banks already

operating under a license from PharmaStem." (emphasis added) A sample of this communication is attached hereto as Exhibit 7.

- 2004, after the Court in the Competitor Litigation issued its Order finding no infringement of the '553 Patent and granting a new trial on infringement of the '681 Patent. The September 20 Press Release mischaracterizes the Court's ruling as well as defendants' positions in the Competitor Litigation. For example, PharmaStem states that defendants argued that families who bank blood with them could be liable for infringement and that the Court "agreed with the defendants" in that regard. In fact, the basis for the Court's decision was that the defendants did not sell or offer to sell cord blood. Defendants in the Competitor Litigation did not argue that families are liable for infringing PharmaStem's patents; parents do not sell or offer to sell cord blood, and therefore cannot be liable. This is but the latest false implication designed to deter patients from seeking services from ViaCell, Cryo-Cell, CorCell and other private banks without regard to the narrow limitations of PharmaStem's patents. A copy of the press release is attached hereto as Exhibit 8.
- 37. On September 22, 2004, PharmaStem (through its counsel) sent a communication to the American College of Obstetricians and Gynecologists ("ACOG"). According to its website, the ACOG has over 46,000 members and is "the nation's leading group of professionals providing health care for women." The communication states, among other things, that "PharmaStem has filed patent infringement lawsuit against over two dozen physicians who work with the four unlicensed cord blood banks", that the "PharmaStem Amnesty Program has been joined by hundreds of physicians", and that another professional society "has recommended its members join the Amnesty Program as a precautionary measure

against being named as a defendant in a lawsuit." A copy of this communication is attached as Exhibit 9.

- 38. The Press Release of August 2, 2004, the letters of August 18, August 20, and September 14, 2004, the Press Release of September 20, 2004, and the communication of September 22, 2004 to the ACOG, were disseminated after PharmaStem had already made misrepresentations in the earlier PharmaStem June Letter. As such, they served to confirm and bolster the earlier misrepresentations and to perpetuate and reinforce false impressions about the scope of PharmaStem's patents and the risk of liability in the eyes of obstetricians, other health care providers and the public. The press releases, the letters, and the ACOG communication made no attempt to correct the earlier misrepresentations, to disclose the inaccuracies of the earlier misrepresentations, to accurately disclose the ruling of the Court in the Competitor Litigation, or to accurately describe the scope and limitations of PharmaStem's patents. In the Settlement Agreement, the Amnesty Agreement and the cover letters accompanying them PharmaStem failed to disclose the limitations on theories of indirect infringement that Judge Sleet ordered were necessary to avoid deception.
- 39. Even after reversal of the jury verdicts of infringement, PharmaStem continues to display a statement prominently on its website stating: "On October 29, 2003, a Delaware jury unanimously found that . . . ViaCord, CBR (Cord Blood Registry), Cryo-Cell and CorCell had willfully infringed [the '681 and '553] patents." This web page makes no reference to the fact that the Court subsequently overturned those verdicts, and is thus misleading. PharmaStem has refused a request to stop running statements concerning the overturned jury verdict. A printout from the web page dated October 5, 2004, is attached hereto as Exhibit 10.

- 40. Concurrently with this campaign of deception and intimidation, PharmaStem purchased "sponsored links" on Internet search engines, such as Google and Yahoo, in which it identifies ViaCell, Cryo-Cell and CorCell as "unlicensed bank[s]," without direct reference to PharmaStem's patents, and states: "Why Take a Risk?" This advertisement and unauthorized use of ViaCell's, Cryo-Cell's and CorCell's trademarks is designed to, and does, create the misleading impression that ViaCell, Cryo-Cell and CorCell are cord blood banks that are not licensed, for example, by state health departments and, consequently, that they are in imminent danger of being shut down. In fact, ViaCell, Cryo-Cell and CorCell hold all state licenses required to operate a private umbilical cord blood banking service. This conduct constitutes disparagement and unfair and deceptive trade practices.
- The campaign of deception and intimidation undertaken by PharmaStem was 41. intended to create misapprehension in the minds of physicians that they risk potential liability for infringement of the PharmaStem Patents even if they merely collect umbilical cord blood for a patient who is a customer of ViaCell, Cryo-Cell or CorCell. PharmaStem's actions also were designed to dissuade or prevent consumers from purchasing the services the cord blood banks that have not bowed to PharmaStem's extortionate tactics.
- 42. Under no proper interpretation of any claim of the PharmaStem Patents would an obstetrician be liable for patent infringement based merely on collecting umbilical cord blood at the time of a delivery and providing it to the patient for the patient's shipment to a private cord blood bank. PharmaStem does not hold a good faith belief that such conduct by physicians could provide a basis for infringement liability.
- 43. Indeed, such improper threats, based upon such a clearly erroneous interpretation of the statute, of such enforcement constitute a misuse of the PharmaStem Patents. This

conduct also constitutes an improper and anticompetitive attempt to use PharmaStem's patents to cover unpatented activities.

# THE THREATENED AND ACTUAL ANTICOMPETITIVE EFFECTS OF PHARMASTEM'S CONDUCT

- 44. PharmaStem's campaign to coerce a boycott by health care providers against ViaCell, Cryo-Cell, CorCell and other private cord blood banks through the Amnesty Agreements threatens to unreasonably restrain trade in the market for private cord blood banking services. The boycott is intended to coerce, and unless enjoined threatens to have the effect of coercing, all or substantially all private cord blood banks into signing licenses with PharmaStem. Those licenses are wrongful, overbroad, and anticompetitive, because they require blood banks to pay royalties to PharmaStem for activities that do not infringe PharmaStem's patents.
- 45. The Amnesty Agreements that PharmaStem is using to implement its boycott also are improper and anticompetitive. Those agreements, individually and collectively, are designed and intended to deprive consumers of access to private cord blood banks where they do not have to pay an improper overcharge caused by PharmaStem's wrongful licenses. The terms of those agreements are far broader than is necessary to settle any legitimate claims for patent infringement PharmaStem may have against any hospitals or physicians. The overbreadth of those agreements serves no legitimate business purpose of PharmaStem and unduly restricts competition.
- 46. PharmaStem's Amnesty Agreements require the signing physician or hospital to "agree[] not to [1] collect cord blood or [2] market or [3] offer the service of cord blood collection in connection with the unlicensed cord blood banks listed below". The Amnesty

Agreements then list the private cord blood banks that have refused to accept PharmaStem's wrongful licenses. See Exhibit 6 (emphasis added).

- 47. By requiring the hospitals or physicians to agree to a blanket refusal to deal with ViaCell, Cryo-Cell and CorCell, PharmaStem's Amnesty Agreements go substantially beyond any legitimate right to exclude arising from PharmaStem's patents. The Amnesty Agreements improperly prevent hospitals and doctors from performing services in connection with ViaCell, Cryo-Cell and CorCell that do not infringe any claim in any of PharmaStem's patents.
- 48. According to PharmaStem, "80% of the private umbilical cord blood companies in the United States are now operating under its licensed patents." That means that those companies are now paying royalties to PharmaStem pursuant to those licenses. The license agreements are improper and anticompetitive to the extent they require blood banks to pay royalties to PharmaStem for activities that do not infringe PharmaStem's patents.
- 49. According to PharmaStem, hundreds of doctors have signed PharmaStem's Amnesty Agreements as of the date of this filing. ViaCell, Cryo-Cell and CorCell are aware of numerous doctors and hospitals who have stated they will no longer collect blood for patients wishing to store it at ViaCell, Cryo-Cell and CorCell; of course, they do not know how many others have taken the same position without informing ViaCell, Cryo-Cell and CorCell. PharmaStem continues to target doctors and hospitals. As a result, ViaCell, Cryo-Cell and CorCell are being substantially foreclosed from access to cord blood, a necessary input to the business of providing private cord blood banking services. The degree of foreclosure will continue to rise if PharmaStem is allowed to continue with its wrongful course of conduct unchecked.

- In response to PharmaStem's campaign, at least one certain professional society **5**0. advised obstetricians "to exercise extreme caution" and stated that "[t]hose wishing to insulate themselves from any possible litigation may want to execute the [Amnesty] Agreement." See Exhibit 11.
- 51. The Amnesty Agreements are purely private agreements between PharmaStem and the other parties who sign them.
- 52. Certain obstetricians and hospitals have refused, and are refusing, to collect any umbilical cord blood, regardless of the bank where it will be stored, as a result of PharmaStem's conduct. Patients of such doctors who otherwise would collect and preserve umbilical cord blood suffer clear and irreparable harm. Once the opportunity to collect cord blood at the time of birth is foregone or lost, it can never be recovered.
- 53. PharmaStem's wrongful campaign also threatens to give PharmaStem the power to control prices or exclude competition in the market for private cord blood banking services. PharmaStem's power arises from, and is reflected in, its forcing of overbroad license agreements with their attendant royalty fees on private cord blood banks. If PharmaStem succeeds in forcing all or nearly all private cord blood banks to sign such overbroad license agreements, or succeeds through the boycott it is organizing in driving unlicensed private cord blood banks out of business, PharmaStem will have wrongfully acquired monopoly power.
- 54. On information and belief, at least some private cord blood banks have raised the prices they charge to customers for storing cord blood as a result of the royalties they must pay PharmaStem. Most or all of the remaining private banks that have signed licenses are likely to raise their prices as well because of the costs to the banks of the royalty payments.

- 55. Some or all of the royalty fees PharmaStem is charging to private cord blood banks, and some or all of the resulting increase in prices that private cord blood banks charge to families for storage services, constitutes an anticompetitive overcharge. Given the overbroad nature of PharmaStem's licenses, private cord blood banks are paying royalties to PharmaStem (and charging customers for the costs of those royalties) in connection with activities that do not infringe PharmaStem's patents. Thus, at least some consumers are already suffering the anticompetitive effects of PharmaStem's anticompetitive scheme.
- 56. If PharmaStem succeeds through its wrongful Amnesty Agreements and other conduct in forcing ViaCell, Cryo-Cell and CorCell to accept PharmaStem's wrongful license, or alternatively drives those companies out of the market, families will be left with no choice but to store their blood with a private bank that is required to pay royalty fees to PharmaStem. As a result, families will have no choice but to pay supracompetitive prices for private cord blood banking services as a result of the anticompetitive overcharge created by PharmaStem's wrongful licenses.

#### THE RELEVANT MARKET

- 57. Starting in the late 1980s, several companies began to offer families a service for the collection and storage of cord blood for potential use in therapeutic transfusions. Cord blood that is collected at the time of delivery for preservation is then transported to other facilities, where it is tested and cryogenically preserved. Facilities that store cord blood are referred to as cord blood "banks." Hospitals do not provide cord blood banking services themselves.
- 58. The only way for cord blood banks to obtain cord blood for storage is for families to decide to preserve cord blood immediately following delivery and elect to store it

with a particular bank. Once cord blood has been collected and preserved at one blood bank, it typically is not sold or transferred to another blood bank for storage.

- 59. There are two types of cord blood banks: private and public. Private blood banks charge parents fees for the collection, transportation, processing, and storage of cord blood. The parents retain ownership over the blood samples stored in private blood banks and may withdraw the blood without cost.
- 60. Public cord blood banks typically do not charge parents for donating cord blood. Public cord blood banks take ownership of the cord blood they store, and typically charge for the use or withdrawal of cord blood samples. Public cord blood banks tend to store only relatively common HFA types, and there is no guarantee that cord blood donated to public banks will be stored. As a result, parents who donate cord blood to public banks have no assurance that the blood they donated would be available for them in the future as do parents who store cord blood at private banks. Nor is it always possible to find a match from an unrelated donor.
- 61. Many consumers view private cord blood banking as a form of insurance. These consumers value knowing that the cord blood would be there should it be needed in the future. Thus, they are willing to pay to have the cord blood stored, even though only a small fraction of the units stored actually get used at a later date for the apeutic transfusions. In addition, clinical studies show that patients who receive cord blood from related donors have higher survival rates than patients who receive cord blood from unrelated donors. Parents who store cord blood in private banks know that the specific blood they stored will be available for them in the future, if necessary.

- 62. Public cord blood banks do not offer this same insurance feature or family benefit. Because public banks take ownership of the blood units, they are entitled to provide the blood units to someone other than the donor family.
- 63. On information and belief, PharmaStem itself does not view public cord blood banks as reasonable substitutes for, or to be reasonably interchangeable with, private cord blood banks. Among other things, in PharmaStem's communications with doctors, PharmaStem's references to cord blood banks routinely list only private banks, without mentioning public banks.
- 64. The provision of private cord blood banking services in the United States constitutes a relevant market for purposes of the antitrust laws.

# THREATENED AND ACTUAL INJURY TO VIACELL, CRYO-CELL AND CORCELL

- 65. The improper boycott PharmaStem is implementing against ViaCell, Cryo-Cell and CorCell is causing substantial damage to their business and threatens to cause additional such damage unless PharmaStem's conduct is enjoined.
- 66. ViaCell, Cryo-Cell and CorCell will be irreparably harmed as a direct and proximate result of PharmaStem's conduct alleged herein unless PharmaStem is enjoined. That irreparable will include, but not be limited to, loss of goodwill, loss of business, and loss of customers. Those harms cannot be adequately remedied through money damages.
- 67. As a direct and proximate result of PharmaStem's conduct alleged herein, including the false and misleading statements PharmaStem has made and the Amnesty Agreements PharmaStem has imposed on health care providers, ViaCell, Cryo-Cell and CorCell also have lost business and are threatened with continuing loss of business from families who otherwise would store cord blood for preservation with ViaCell, Cryo-Cell or

CorCell but who now have not and will not do so. As a result of this lost business, ViaCell, Cryo-Cell and CorCell are losing and are threatened with continuing loss of revenues they otherwise would receive and profits they otherwise would earn from storing cord blood.

- 68. In the past few weeks, hospitals and physicians have informed ViaCell, Cryo-Cell and CorCell that they will no longer collect cord blood for patients to supply to ViaCell, Cryo-Cell and CorCell for preservation. Customers of ViaCell, Cryo-Cell and CorCell have also discontinued their plans to store blood at ViaCell, Cryo-Cell and CorCell because their doctors refused to perform the collection. Other hospitals and medical practices have discontinued cord blood collections altogether, resulting in further business losses for ViaCell, Cryo-Cell and CorCell. Various physician associations are advising their members not to collect cord blood for storage by the blood banks that have refused PharmaStem's licenses. Hospitals' and physicians' unwillingness to collect cord blood for families who wish to store the blood with ViaCell, Cryo-Cell and CorCell results directly from PharmaStem's wrongful conduct as alleged herein.
- 69. The injury to ViaCell, Cryo-Cell and CorCell resulting from PharmaStem's conduct constitutes antitrust injury.

#### COUNT I

## (For Declaratory Judgment under 28 U.S.C. § 2201 Based on Threatened and Actual Violations of the Antitrust Laws)

- 70. ViaCell, Cryo-Cell and CorCell repeat and incorporate the allegations of Paragraphs 1 through 69 as if set forth here in full.
- 71. ViaCell, Cryo-Cell and CorCell assert this claim for declaratory judgment pursuant to 28 U.S.C. § 2201 et seq.
- 72. There is an actual controversy between ViaCell, Cryo-Cell and CorCell, on one hand, and PharmaStem on the other concerning the lawfulness of PharmaStem's conduct as

described in this complaint under the federal antitrust laws, the federal Lanham Act, and other state laws.

**73**. ViaCell, Cryo-Cell and CorCell seek a declaration that PharmaStem's conduct, as described in this Complaint, impermissibly threatens to restrain trade in and has restrained trade in, impermissibly attempts to monopolize, and impermissibly threatens to monopolize the relevant market, all in violation of the federal antitrust laws, 15 U.S.C. § 1 et seq., and in violation of other federal and state law, and justifies the granting of relief to ViaCell under Section 16 of the Clayton Act, 15 U.S.C. § 26.

## COUNT II

## (Violation of 15 U.S.C. § 1 -Threatened Restraint of Trade - Injunctive Relief)

- 74. ViaCell, Cryo-Cell and CorCell repeat and incorporate the allegations of Paragraphs 1 through 73 as if set forth here in full.
- *75*. The provision of private cord blood banking services in the United States constitutes a relevant product market.
- 76. PharmaStem has entered into agreements in restraint of trade with numerous hospitals and/or physicians and, unless enjoined, threatens to enter into additional such agreements in restraint of trade with other hospitals and/or physicians.
- *7*7. The agreements PharmaStem has entered into, and threatens to enter into, with hospitals and/or physicians do and will constitute a substantial and unreasonable restraint of trade.
- 78. The agreements PharmaStem has entered into, and threatens to enter into, with hospitals and/or physicians do and will have a substantial effect on interstate commerce.
- 79. The agreements PharmaStem has entered into, and threatens to enter into, with hospitals and/or physicians threaten to cause loss or injury to ViaCell, Cryo-Cell and CorCell.

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- 80. The loss or injury with which ViaCell, Cryo-Cell and CorCell are threatened as a result of PharmaStem's unreasonable agreements in restraint of trade does and will constitute antitrust injury.
- 81. The threat of loss or injury from PharmaStem's conduct is substantial and immediate.
- 82. ViaCell, Cryo-Cell and CorCell are entitled to preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 26 against threatened loss or damage in violation of the antitrust laws, including without limitation Section 1 of the Sherman Act, 15 U.S.C. § 1.

### **COUNT III**

## (Violation of 15 U.S.C. § 2-Threatened Monopolization - Injunctive Relief)

- 83. ViaCell, Cryo-Cell and CorCell repeat and incorporate the allegations of Paragraphs 1 through 82 as if set forth here in full.
- 84. The provision of private cord blood banking services in the United States constitutes a relevant product market.
- 85. PharmaStem threatens to violate Section 2 of the Sherman Act (15 U.S.C. § 2) by willfully and unlawfully acquiring monopoly power in the relevant market by engaging in its ongoing and continuous pattern of exclusionary and anticompetitive conduct, as alleged above, including but not limited to:
  - (a) making false and misleading statements to doctors, hospitals, families, and the public;
  - (b) intimidating doctors and hospitals through objectively unreasonable and overbroad actual or threatened claims of potential patent liability; and

- (c) entering into wrongful and overbroad licensing agreements with certain private cord blood banks that require the payment of royalties to PharmaStem even for activities that do not infringe any claim of PharmaStem's patents; and
- (d) entering in wrongful and overbroad "Amnesty Agreements" or other agreements with doctors and/or hospitals that require the doctors and/or hospitals to boycott the private cord blood banks that have refused PharmaStem's wrongful license demands, thereby preventing even non-infringing activities.
- 86. PharmaStem's conduct threatens to cause injury to competition in the form of, among other things, higher prices paid by consumers for private cord blood banking services than they would pay but for PharmaStem's wrongful conduct.
- 87. PharmaStem's conduct threatens to injure ViaCell, Cryo-Cell and CorCell in the form of, among other things, lost profits resulting from lost opportunities to provide cord blood banking services as a result of PharmaStem's wrongful conduct, including but not limited to the Amnesty Agreements.
- 88. PharmaStem's improper and anticompetitive conduct will be a direct and proximate cause of the threatened injuries to competition and to ViaCell, Cryo-Cell and CorCell complained of herein.
- 89. The threat of injury and loss from PharmaStem's wrongful conduct is immediate and substantial.
- 90. The injuries that PharmaStem's conduct threatens to cause to ViaCell, Cryo-Cell and CorCell are of the type that the Sherman and Clayton Acts were intended to prevent and flow from that which makes PharmaStem's acts unlawful under the Sherman and Clayton Acts.

- 91. PharmaStem's conduct has, and threatens to have, a substantial affect on interstate commerce.
- 92. ViaCell is entitled to preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 26 against threatened loss or damage in violation of the antitrust laws, including without limitation Section 2 of the Sherman Act, 15 U.S.C. § 2.

### **COUNT IV**

(Violation of 15 U.S.C. § 1 –Unreasonable Restraint of Trade – Damages)

- 93. ViaCell, Cryo-Cell and CorCell repeat and incorporate the allegations of Paragraphs 1 through 92 as if set forth here in full.
- 94. The provision of private cord blood banking services in the United States constitutes a relevant product market.
- 95. PharmaStem has entered into agreements in restraint of trade with numerous hospitals and/or physicians.
- 96. The agreements PharmaStem has entered into with hospitals and/or physicians substantially and unreasonably restrain trade.
- 97. The agreements PharmaStem has entered into with hospitals and/or physicians have had a substantial effect on interstate commerce.
- 98. PharmaStem's conduct has injured competition through, among other things, higher prices paid by consumers for private cord blood banking services than they would pay but for PharmaStem's wrongful conduct.
- 99. PharmaStem's conduct had injured ViaCell, Cryo-Cell and CorCell through, among other things, lost profits resulting from lost opportunities to provide cord blood banking services as a result of PharmaStem's wrongful conduct, including but not limited to the Amnesty Agreements.

- 100. PharmaStem's improper and anticompetitive conduct has directly and proximately caused the injuries to competition and to ViaCell, Cryo-Cell and CorCell complained of herein.
- 101. These injuries from PharmaStem's conduct constitute antitrust injury and are of the type that the Sherman and Clayton Acts were intended to prevent and flow from that which makes PharmaStem's acts unlawful under the Sherman and Clayton Acts.
- 102. ViaCell, Cryo-Cell and CorCell are entitled to damages pursuant to Section 4 of the Clayton Act. 15 U.S.C. § 15, including treble damages, reasonable attorneys' fees, and costs, for the losses suffered from PharmaStem's violation of the antitrust laws, including without limitation Section 1 of the Sherman Act, 15 U.S.C. § 1.

# COUNT V (Violation of 15 U.S.C. § 2 – Attempted Monopolization – Damages)

- 103. ViaCell, Cryo-Cell and CorCell repeat and incorporate the allegations of Paragraphs 1 through 102 as if set forth here in full.
- 104. There is a dangerous probability that PharmaStern will acquire monopoly power in the market for private blood banking services in the United States.
  - 105. PharmaStem has acted with specific intent to monopolize.
- 106. PharmaStem is engaging in its ongoing and continuous pattern of exclusionary and anticompetitive conduct in furtherance of its attempt to monopolize, as alleged above, including but not limited to:
  - (a) making false and misleading statements to doctors, hospitals, families, and the public;
  - (b) intimidating doctors and hospitals through objectively unreasonable and overbroad actual or threatened claims of potential patent liability; and

- entering into wrongful and overbroad licensing agreements with certain (c) private cord blood banks that require the payment of royalties to PharmaStem even for activities that do not infringe any claim of PharmaStem's patents; and
- (d) entering in wrongful and overbroad "Amnesty Agreements" or other agreements with doctors and/or hospitals that require the doctors and/or hospitals to boycott the private cord blood banks that have refused PharmaStem's wrongful licenses, thereby preventing even non-infringing activities.
- PharmaStem's conduct has had a substantial effect on interstate commerce. 107.
- PharmaStem's conduct has injured competition through, among other things, 108. higher prices paid by consumers for private cord blood banking services than they would have paid but for PharmaStem's wrongful conduct.
- PharmaStem's conduct has injured ViaCell, Cryo-Cell and CorCell through, 109. among other things, lost profits resulting from lost opportunities to provide cord blood banking services as a result of PharmaStem's wrongful conduct, including but not limited to the Amnesty Agreements.
- PharmaStem's improper and anticompetitive conduct has directly and 110. proximately caused the injuries to competition and to ViaCell, Cryo-Cell and CorCell complained of herein.
- These injuries from PharmaStem's conduct constitute antitrust injury and are of 111. the type that the Sherman and Clayton Acts were intended to prevent and flow from that which makes PharmaStem's acts unlawful under the Sherman and Clayton Acts.
- 112. ViaCell, Cryo-Cell and CorCell are entitled to damages pursuant to Section 4 of the Clayton Act. 15 U.S.C. § 15, including treble damages, reasonable attorneys' fees, and

costs, for the losses suffered from PharmaStem's violation of the antitrust laws, including without limitation Section 2 of the Sherman Act, 15 U.S.C. § 2.

## **COUNT VI** (Federal Unfair Competition in violation of the Lanham Act 15 U.S.C. § 1125(a))

- ViaCell, Cryo-Cell and CorCell repeat and incorporate the allegations of 113. Paragraphs 1 through 112 as if set forth here in full.
- PharmaStem has made false and misleading statements as to the services 114. ViaCell, Cryo-Cell and CorCell provide.
- 115. PharmaStem's statements create an actual deception or at least a tendency to deceive a substantial portion of PharmaStem's intended audiences.
- The deception is material and is likely to influence decisions by families who 116. may desire to have their child's cord blood preserved by ViaCell, Cryo-Cell and CorCell, either directly or by causing physicians and hospitals to refuse to collect cord blood for such patients, or by causing physicians to discourage patients from storing cord blood with those blood banks.
- These services are provided and sold in and affect a substantial amount of 117. interstate commerce.
- There is a likelihood that ViaCell, Cryo-Cell and CorCell have been and will be injured by PharmaStem's false statements, including in the form of lost business by customers who either do not store cord blood or store it with a different blood bank.
- ViaCell, Cryo-Cell and CorCell are entitled to compensatory damages and an injunction against further false statements by PharmaStem.

#### COUNT VII

(Unfair and Deceptive Trade Acts, Practice, and Competition in violation of Mass. Gen. Laws Chapter 93A, §§ 2 and 11)

- 120. ViaCell repeats and incorporates the allegations of Paragraphs 1 through 119 as if set forth here in full.
- 121. PharmaStem is engaged in trade or commerce as defined by Mass. Gen. Laws
  Chapter 93A, § 2.
- 122. PharmaStem's conduct as alleged in this complaint constitutes unfair and deceptive trade acts and practices and unfair competition, in violation of Chapter 93A.
  - 123. PharmaStem's violation of Chapter 93A was willful and knowing.
  - 124. PharmaStem's conduct took place primarily and substantially in Massachusetts.
  - 125. ViaCell has been injured by PharmaStem's unlawful conduct.
- 126. ViaCell is entitled to recover single and multiple damages for its injuries, attorneys fees, and costs pursuant to Mass. Gen. Laws Chapter 93A, § 11. ViaCell also is entitled to injuctive relief pursuant to Mass. Gen. Laws Chapter 93A, § 11.

# COUNT VIII (Tortious Interference with Contract)

- 127. ViaCell, Cryo-Cell and CorCell repeat and incorporate the allegations of Paragraphs 1 through 126 as if set forth here in full.
- 128. ViaCell, Cryo-Cell and CorCell have valid contracts or business relationships with families to provide private cord blood banking services that contemplate economic benefit to ViaCell, Cryo-Cell and CorCell.
  - 129. PharmaStem knew about these contracts and business relationships.
- 130. PharmaStem interfered with these contracts and business relationships for improper purposes and by improper means.
  - 131. PharmaStem's conduct warrants condemnation and deterrence.

- 132. ViaCell, Cryo-Cell and CorCell have suffered damages as a result of PharmaStem's interference.
- 133. ViaCell, Cryo-Cell and CorCell are entitled to recover compensatory and punitive damages for their injuries.

# <u>COUNT IX</u> (Tortious Interference with Prospective Advantageous Relationships)

- 134. ViaCell, Cryo-Cell and CorCell repeat and incorporate the allegations of Paragraphs 1 through 133 as if set forth here in full.
- 135. ViaCell, Cryo-Cell and CorCell have present and past prospective advantageous relationships with families to provide private cord blood banking services that contemplate economic benefit to ViaCell, Cryo-Cell and CorCell.
  - 136. PharmaStem knew about these prospective advantageous relationships.
- 137. PharmaStem interfered with these prospective advantageous relationships for improper purposes and by improper means.
  - 138. PharmaStem's conduct warrants condemnation and deterrence.
- 139. ViaCell, Cryo-Cell and CorCell have suffered damages as a result of PharmaStem's interference.
- 140. ViaCell, Cryo-Cell and CorCell are entitled to recover compensatory and punitive damages for their injuries.

#### COUNT IX

## (Unfair and Deceptive Trade Practices in violation of Fla. Stat. § 501.201, et seq.)

- 141. Cryo-Cell repeats and incorporates the allegations of Paragraphs 1 through 140 as if set forth here in full.
- 142. PharmaStem's conduct as alleged in this complaint constitutes deceptive and unfair trade practices in violation of the Florida Deceptive and Unfair Trade Practices Act.

143. Cryo-Cell has been injured by PharmaStem's unlawful conduct, and are likely to suffer further damage unless said conduct is restrained. Cryo-Cell is entitled to recover damages and counsel fees as a result of PharmaStem's violation.

## PRAYER FOR RELIEF

WHEREFORE, ViaCell, Cryo-Cell and CorCell ask that the Court:

- A. Grant a declaratory judgment that PharmaStem's conduct alleged in this Complaint threatens to violate, and violates, the federal antitrust laws, 15 U.S.C. § 1 et seq.;
- B. Enter a preliminary and permanent injunction enjoining PharmaStem's ongoing wrongful conduct, including but not limited to enforcement of the Amnesty Agreements, pursuant to, inter alia, 15 U.S.C. § 26 and Mass. Gen. Laws Chapter 93A, § 11;
- C. Award treble damages, attorneys' fees, and costs pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15, for PharmaStem's violations of the federal antitrust laws, 15 U.S.C. § 1 et seq.;
- D. Award ViaCell single and multiple damages, attorneys' fees, and costs pursuant to Mass. Gen. Laws Chapter 93A, § 11, based on PharmaStem's unfair and deceptive trade acts and practices and unfair competition in violation of Chapter 93A, § 2;
- E. Award Cryo-Cell compensatory damages, attorneys' fees, and costs pursuant to the Florida Deceptive and Unfair Trade Practices Act, based on PharmaStem's unfair and deceptive trade acts and practices and unfair competition in violation of Chapter 93A, § 2;
- F. Award ViaCell, Cryo-Cell and CorCell compensatory and punitive damages; and 32

G. Grant ViaCell, Cryo-Cell and CorCell such other and further relief as the Court

deems just and proper.

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First Federal Plaza

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(302) 571-9800

On behalf of Cryo-Cell International, Inc.

and CorCell, Inc.

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On behalf of Cryo-Cell International, Inc. and
CorCell, Inc.

Tab 1

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PAGE 01

FROM :

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PHARMASTEM

June 1, 2004

Dear Or. Gold.

We have been asked by concerned colleagues of yours to clarify the legs) implications for Obstetricians regarding the collection of umbilical cord blood.

The question raised by your colleagues relates to the <u>Obstetrician's legal liability</u> arising out of infringement of U. S. patents 5,004,661, 5,192,553, 8,481,645, 8,589,427 and 5,505,275 owned by PharmaStem Therapeutics. Patent infringement occurs when a paraon or institution practices all or part of a patented process. In the case of umbilical cord bicod collection by an Obstetrician, the Court ruled that infringement occurs even if the cryopreservation and plorage is performed by a third party.

Sensitive to the delicate position you are confronted with, PharmaStern wants to assure you that we have taken all the necessary steps to protect the Obstetricians from any intellectual property infringement liability, provided they work with any one of the following itemsed companies:

Stembanc Cord Blood Family Trust StemCyte Newborn Blood Banking Securacell LifeBank USA Family Link Norton Hospitals Cord Partners HemaStem Therapeutics Galifornia Cryobank Lifestor New England Cord Blood Bank Alpha Cord

In its license agreements with these cord blood banks, PharmaSiem has extended its license to the health care providers under the condition they work with these licensed Blood banks:

"The license granted shall extend to any medical doctor, nurse, midwife, hospital, clinic.... (collectively, "Health Care Providers"],...involved in the Collection, ...of any Cord Blood,... that will be Cryopreserved, by the licensed Cord Blood Bank ..."

This language means that as long as you are collecting cord blood for a PharmaStem licensed blood bank, you are not liable for patent infringement.

In October 2003 a Federal jury in the United States Federal Court, District of Delaware unanimously found that ViaCeli / ViaCerd, CBR Systems, ("Cord Blood Registry"), Cryo-Cell International and CorCell willfully Infringe PharmaStam's patisnis covering the polection, cryopreservation and storage for future therapeutic use of stam cells derived from umbifical cord blood. Following this verdict, PharmaStam has asked the Court to grant a permanent injunction against these companies. An Injunction would prevent the infringing companies from continuing their cord blood storage activities.

Scientists at PharmaStam, through its predecessor Biocyte, not only discovered the therapeutic benefits of umbilical cord blood for treatment of certain diseases, but also organized and funded the first successful umbilical cord blood transplant in 1988. If you would like to learn more about PharmaStem Therapeutics and its pioneering patents, visit www.pharmastem.com.

Regards,

Nicholas Dialies

Nicholas Didler CEO & President PharmaStern Therapeutics, Inc. natidiardipharmastern.com Case 1:04-cv-11673-RWZ Document 29-3 Filed 11/16/2004 Page 37 of 65

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#### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

PHARMASTEM THERAPEUTICS, INC.,	}
Plaintiff,	}
γ.	Civil Action No. 02-148-GMS
VIACELL, INC., et al.,	<b>\( \)</b>
Defendants.	<b>)</b>

ORDER

Upon consideration of Defendants' Motion for Injunctive Relief While Court's Ruling on Post-Trial Motions is Pending, including supporting material and argument, and all Opposition papers, supporting material and argument, the Court hereby FINDS:

- 1. PharmaStem's June 1, 2004 letter to Obstetricians (the "PharmaStem Letter")
  contains false and misleading statements concerning this Court's rulings to date. In particular,
  the Court finds the following statements in this PharmaStem Letter false and misleading:
- A. "Patent infringement occurs when a person or institute practices all or part of a patented process." The Court finds this statement is misleading because it is black letter law that in order to prove contributory infringement of a method patent, the entire patented process must be performed. By suggesting that infringement would occur when only part of a process is performed, the letter is misleading.
- B. "In the case of umbilical cord blood collection by an obstetrician, the Court ruled that infringement occurs even if the cryopreservation and storage is performed by a third party." The Court finds this statement misleading for at least the following reasons. First, the sentence states that "the Court ruled" with respect to the "case" of "umbilical cord blood collection by an Obstatrician." This Court never made any rulings regarding conduct by

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PAGE 96/88

obstetricians. There were no such allegations advanced in the trial of this matter. Second, the sentence leaves out several important elements that must be proved to show contributory infringement. This missing elements include:

- (1) that there must be a sale or offer to sell by the party that is accused of contributory infringement,
- (2) that the party accused of contributory infringement must be "acting in concert or working together" with the other parties whose combined conduct performed each and every element of the patented process, and
- (3) that, under §271(c), a sale of a service, as opposed to a sale of a tangible physical object, is not sufficient to satisfy the requirements of the contributory infringement statute.

The Court finds that without these elements, the statement is misleading.

- PharmaStem is ordered to provide to Defendants within 10 days of this Order a list of all persons to whom the Letter was sent.
- 3. The Court also hereby ORDERS that PharmaStem is prohibited from making any further false or misleading communications to obstetricians.

Dated July 2, 2004

DI TO STATES DISTRICE TUDGE

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August 2, 2004

PharmaStem Therapeutics Initiates New Lawsults Against ViaCell, Cryo-Cell International, Cord Blood Registry (CBR Systems), Corcell and Certain Obstetricians to Protect Its Umbilical Cord Blood Stem Cell Patent Rights

August 2, 2004 - PharmaStern Therapeutics, Inc. announced today that it has initiated multiple lawsuits for patent infringement to protect its intellectual property rights relating to umbilical cord blood stem cells. PharmaStem is the successor to Biocyte Corporation, the pioneer in the discovery and development of umbilical cord blood preservation and its therapeutic use. In recognition of its leadership, PharmaStem has received five U.S. Patents to date for its technological advances.

The new lawsuits assert infringement of two recently issued patents, U.S. Patent Nos. 6,569,427 and/or 6,605,275, which relate to the cryopreservation and therapeutic use of umbilical cord blood stem cells. Named in the complaints are the four remaining cord blood banks (ViaCell, Inc., Cryo-Cell International, Inc., CBR Systems, Inc. (Cord Blood Registry), CorCell, Inc.) who have refused to license PharmaStem's patents and certain obstetricians and health care providers who collect umbilical cord blood for these unlicensed cord blood banks.

Nicholas Didier, President and CEO of PharmaStern stated: "While we would prefer not to sue any obstetricians or health care providers, it is important to protect our intellectual property rights for the benefit of our licensees. To date, we have 15 licensed cord blood banks so obstetricians and health care providers have many choices available to them." PharmaStern's license agreements provide a license to obstetricians and health care providers for the collection of umbilical cord blood provided they work with licensed banks.

PharmaStem currently has licensed its patent portfolio to the following cord blood banks:

LifeBank USA
Stembanc
StemCyte / Cord Blood Family Trust
GeneAngel
Newborn Blood Banking
Securacell
Norton Hospitals Family Link
Cord Partners
HemaStem Therapeutics
Lifestor
California Cryobank Stem Cell Services
New England Cord Blood Bank
Alpha Cord
Cryobanks International
CORD — Cryobank for Oncologic and Reproductive Donors

On October 29, 2004, a Delaware jury unanimously found that two of PharmaStem's pioneering patents, US Patent Nos. 5,004,681 and 5,192,553 were valid and enforceable and that the four defendants, ViaCell, Cryo-Cell, Corcell and CBR Systems (Cord Blood Registry) had willfully infringed these patents.

To learn more about PharmaStem Therapeutics please visit www.pharmastem.com or contact Nicholas Didier, CEO, at 914-833-9227 (phone) or ndidier@pharmastem.com.

Tab 4

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PHARMA**STEM** 

49 PROSPECT AVENUE - LARCHMONT, NY 10534 CHIEF EXECUTIVE OFFICER: 914-653-9227 FAX: 914-833-3175

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DEAR DR HAGADORN,

I LEFT YOU A MESSAGE TO CALL REGARDING LEGAL CASE SACVI4-921 GLT (ANX) AND WAYS TO SETTLE THIS CASE IN AN AMICAL AND EXPEDITIOUS WAY.

ATTACHED IS A PROPOSED AGREEMENT BETWEIN YOU AND PHARMASTEM AS PEAINTIFF IN WHICH WE AGREE TO RELEASE YOU FROM ALL CHARGES AGAINST YOU AND DISMISS YOU FROM THE CASE PLOVIDED YOU AGREE NOT TO COLLECT COLD BLOOD OR MARKET OR OFFER THE SERVICE OF CORD BLOOD COLLECTION IN CONNECTION WITH THE UNLICENSED CORD BLOOD BANKS CER, VIACORD, CRYO-CELL, CORCELL AND CURESOURCE.

OVER THE LAST FEW DAYS, WE HAVE SIGNED AGREEMENTS WITH A NUMBER OF YOUR COLLEAGUES AND CO-DEFENDANTS AND OFFER YOU THE OPPORTUNITY TO DO LIKEWISE

As you probably know, Pharmastem has licenses with futitien cord blood. Banks so you definitely have a choice whom to work with in the futule.

IF THE ATTACHED IS ACCEPTABLE TO YOU, PLEASE SIGN AND DATE ON PAGE 2, INITIAL AND DATE ALL PAGES AND FAX BACK TO US AT 914-853-3175. WE THEN WILL EXECUTE THE AGREEMENT AND TAKE CARE OF THE DISMISSAL

IP YOU HAVE ANY QUESTIONS REGARDING THIS MATTER, PLEASE DO NOT HESITATE TO CAIL ME DIRECTLY AT 914-833-9227

YOURS SINCERELY.

NICHOLAS DIDIER

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AGREEMENT

This is a Agreement (the "Agreement"), entered into as of August 18, 2004, between PharmaStem Therapeutics. Inc., a Delaware corporation located at 69 Prospect Avenue, Larchmont, New York: 10538 ("PharmaStem"), and Bruce Hagadom ("Defendant"), a physicism having an address of 16300 Send Canyon Avenue, Suite 311, Irvine, CA 92618.

In consideration of the promises and covenants contained barein, the parties agree as follows:

#### TERMS AND CONDITIONS .

- Definitions. The terms defined below shall have the meanings defined herein, when used in capital letters:
  - s. "Collection", "Collected", "Collecting" or "Collect" means socumulation of or accumulated Cord Blood in a container.
  - b. "Cord Blood" means blood or any blood components (including without limitation Stem Cells)
     collected from a burnen umbilical cord and/or placents.
  - : c: "Effective Date" means the date noted in the first line of this Agreement.
  - d. "Lawsuit" means PharmaStem Therapeutics, Inc. v. CureSource Inc. et al., United States District Court for the Central District of California, Case No. SACV 04-921 CLT(ANd).
  - ThurmaStem's Patents" means U.S. Potents Nos. 5,004,681, 5,192,553, 6,461,645, 6,569,427
     and 6,605,275.

#### Rejease and Diamieral

In consideration of the mutual covenants, conditions and agreements contained herein, and subject to the other provisions of this Agreement, PharmaStern hereby fully and forever releases, discharges, and covenants not to sue or otherwise institute or processes say legal processing against Defendant with respect to any and all liabilities and claims assemed by PharmaStern in the Lawrett or which could have been asserted by Pharmastern in the Lawrett relating to the PharmaStern Patents.

In comideration of the dismissal of the Lawsuit, the mutual coverants, conditions and appearants contained herein, and subject to the other provisions of this Agreement, Definition bereby (I) agrees not to Collect or offer the service of Collecting Cord Blood in connection with the Uniformed Cord Blood Banks listed on Exhibit A, and (II) fully and forever releases, discharges, and coverants not to spe or otherwise institute or proceeding against PharmaStein with respect to any and all liabilities and counterclaims assected by Defindant in the Lawsuit or which could have been assected by Defindant in the Lawsuit or which could have been assected by Defindant from Collecting or offering the service of Collecting Cord Blood in connection with the Liceared Cord Blood Banks Hand on Exhibit B.

Defendant:	Pharms	Status .		•
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> Upon execution of this Agreement, PharmaStern will file with the Court a stipulation to dismiss all cisims springt Definient with perjudice. Each party agrees to best responsibility for all stimmers' first, expenses and costs that it has accrued in relation to the Lawrent

Term. The term of this Agreement shall commence on the Effective Date and terminate on March 9, 2010, unless this Agreement is sooner terminated in accordance with its terms.

#### Termination.

This Agreement may be canceled by either party upon thirty (30) days prior written recice, if the other party is in breach of any of its marerial obligations becounder. In the event Defendant Collects or offices the service of Collecting Cord Blood in connection with any of the Unlicensed Cord Blood Banks Heted on Bobilds A after the Effective Date of this Agreement, and PharmaSpan prevails in an action against Defindant in connection with such event, PharmaSuca shall be entitled to its coses of suit and attorneys' feet from Defindant.

#### Miscellaneous.

<u>.</u>;

- 2. Defendant agrees that PharmaStom may disclose to others the existence and nature of this Agreement,
- This Agreement (including the Exhibits attached hereto) shall be deemed to contain the complete and final agreement between the parties, and shall superscale all provious understandings relating to the guidest matter hornof, whether oral or written. This Agreement may only be modified by a written agreement signed by duly authorized representatives of the pertical
- This Agreement may be executed in two or more equatorparts (including by faceintile), each of which shall be deemed an original, but all of which taken together shall constitute one and the same Agreement. A facsimile copy of any signature shall serve as an original for all purposes.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed on August 18:2004.

By: Nicholas V. Didlet, its CBO	-		
Dr. Bruce Hagadorn	•	.•	
	<u>-:</u>	•	
Defendanti	•	Pharme Stem:	
Dates	• •	Date:	

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CorCell, Inc.
Cord Blood Registry, Inc. (d/b/e CBR)
Cryo-Cell International, Inc.
CureSource, Inc.
ViaCell, Inc. (d/b/e ViaCord)

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EXHIBIT B

Alpha Cord
California Cryobank
CORD — Cryobank for Oncologic and Reproductive Donors
Cord Partners
Cryobanks International
GeneAngal
HernaStem Therapantics
LifeBank USA
Eliberor
Fiew England Cord Blood Bank
Newborn Ricod Banking
Norton Hospitals/Family Link
Securacell
StemBane
SternCyte / Cord Blood Family Trust

Defendent: \_\_\_\_\_\_ PharmaStem: \_\_\_\_\_\_
Date: \_\_\_\_\_\_

Tab 5

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ANTHOMMERI

PAGE 01

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PHARMASTEM INC.

Dear Dr. Stephen Turner.

August 20, 2004

I am writing to provide an update regarding the recent lawsuits filed across the United States against obstetricians who continue to collect cord blood or market services, including distribution of literature, for the 5 remaining UNLICENSED cord blood banks: ViaCord, CBR (Cord Blood Registry), Cryo-Cell, Corcell and CureSource.

Recently, a lawsuit was filed in the Contral District Court of California against obstetricians who are alleged to have collected cord blood and/or marketed services for unlicensed cord blood banks. I am pleased to report that two weeks later, a number of obstetricians have settled with PharmaStem by signing agreements substantially similar to the enclosed Amnesty Agreement.

Four other lawsuits initiated in Boston, Philadelphia, Tampa and San Francisco against certain obstetricians and hospitals also continue to move forward.

PharmaStern will vigorously defend its Intellectual property rights against obstetricians if they continue to work with unlicensed cord blood banks. It is PharmaStern's position, as asserted in the recent lawsuits, that obstetricians are liable for patent infringement if they collect cord blood or market services for unlicensed cord blood banks.

in an effort to avoid legal action from PharmaStem relating to its patents, please review and sign the attached Amnesty Agreement which, in relevant part, provides the following:

- The obstetrician agrees to stop collecting cord blood or marketing services, including distribution of literature, for unilcensed cord blood banks.
- PharmaStem in exchange covenants not to sue and agrees to release the obstetrician in full from future legal action for past activities.

PharmaStem has currently licensed 15 cord blood banks and urges you to continue the collection of life saving cord blood for your patients by using any of these LIÇENSED banks:

Stembanc
LifeBank USA
Cord Blood Family Trust
GeneAngel
Newborn Blood Banking
Securaceli

California Cryobank Stem
Cell Services
Family Link

Cord Partners
HemaStem Therapeutics
Lifestor

New England Cord Blood Bank

To learn more about PharmaStem Therapeutics, its patent portfolio and licensed cord blood banks please visit <a href="https://www.pharmastem.com">www.pharmastem.com</a>.

Regards.

Nicholan Dislien

Nicholas Oldier CEO & President ndidier@oharmastem.com Please review, sign and date enclosed Amnesty Agreement

· 15 Top Bracket and Silv

Signature:

Date:

Signature: Nicholan Diolina

Date: August 20, 2004

PHARMASTEM

69 Prospect Avenue Larchmont, NY 10538

Caria Wells, MD 4050 Berrenca Parkway Irvine, CA 92604

September 14, 2004

Dear Dr. Wells,

I write on behalf of PharmaStern Therapoutics, Inc., plaintiff in the current patent litigation against you, solely for the purpose of offering to settle this litigation with you.

Patent litigation in Federal court involves considerable time, expense, intrusion, and other inevitable tangible and intangible costs that I believe all parties would like to avoid. For example, just during the discovery process alone, it is likely that you will need to sacrifice several days on:

- o personal deposition as a fect witness
- o likely deposition(s) as a 30/b)(8) witness

You will have to compile and make available

- o all relevant business records
- o all relevant medical records

You will have to develop:

- o written responses to interrogatories regarding your medical practice
- o written responses to interrogationes regarding your business dealings

As to your staff and associates, they will have to spend days in:

a depositions as fact witnesses

The drain on your time and energy if the case proceeds to trial is even greater than the discovery process. All of this can be avoided with a simple settlement agreement at absolutely no cost (money or time) to you.

THIS COMMUNICATION IS GOVERNED BY RULE 408 OF THE FEDERAL RULES OF EVIDENCE AND IS FCR SETTLEMENT PURPOSES ONLY

By: HP LaserJet 3100;

I understand that Gord Blood Registry ("CBR") has provided you with certain assurances with regard to defending this suit, including legal defense through Pilabury, Winthrop. However, whatever those assurances are, they cannot account for your time, the time of your staff and associates, and intrusion on your life and medical practice that such litigation causes. Moreover, CBR cannot remove any personal liability against you if you are found to infringe PharmaStem's patent(s). All PharmaStem is asking is for you to join hundreds of physicians in the obstetrician community (including several of your co-defendants in this case) who have already agreed not to promote the services or collect umbilical cord blood for the few (20%) cold blood banks'that have chosen not to take a license to PharmaStem's patents.

As you may know, the original and seminal work of the Inventors of PharmaStem's patents was recently validated by a full trial in the Federal District Court of Delaware resulting in jury findings of willful patent infringement, patent validity, and patent enforceability against four cord blood banks, including CBR. PharmaStem strongly believes in the medical contribution that our inventors have made in the field of cryppreserving umbilical cord blood for future therapeutic use and is committed to protecting its patent intellectual property.

At the same time, PharmaStem is also committed to the promotion of cord blood backing and the equitable distribution of its benefits to as many potential patients as possible. To that end, PharmaStem has now licensed 80% (16 out of the 20) of the private cord blood banks in the United States. Together, we can ensure that there is no disruption of services to any of your patients who choose to store their baby's cord blood with private cord blood banks. In order to do so, however, we require your cooperation in agreeing to collect only for one of the many cord blood banks already operating under a license from PharmaStem. I would be happy to provide or direct you to information about PharmaStem's itemsed banks, their accreditation, and the high quality of their service and product of takings. Frankly, I can see no downside for you in resolving this dispute and, at the very least, avoiding the cloud of a lawsuit at absolutely no cost to you whatsoever.

Please feel free to call me directly if you wish to discuss the possibility of a settlement or compromise that would result in your full dismissal from the case at hand. However I would suggest that you contact us as soon as possible, as time is of the essence. Once PharmaStem has incurred significant digation costs, it makes no sense for us not to prosecute violators to the fullest extent of the law.

Sincerely,

Nila la Distien

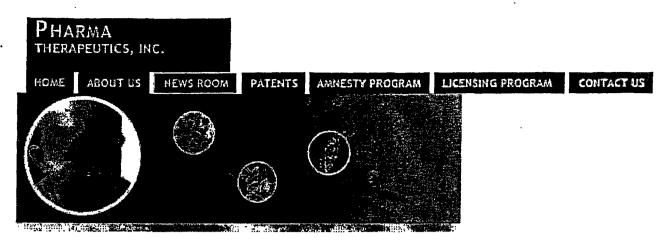
Nicholas Didier CEO and President 914-833-9227 (direct line) ndidier@phannastem.com

THIS COMMUNICATION IS GOVERNED BY RULE 408 OF THE FEDERAL RULES OF EVIDENCE AND IS FOR SETTLEMENT PURPOSES ONLY

Tab 8

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Case 1:04-cv-11673-RWZ Document 29-3 Filed 11/16/2004 Page 56 of 65



# NEWS ROOM PRESS RELEASES

September 20, 2004 August 23, 2004 August 2, 2004 April 22, 2004 March 12, 2004 March 8, 2004 February 12, 2004 February 4, 2004 January 30, 2004 December 3, 2003 November 4, 2003 September 23, 2003 September 8, 2003 February 20, 2003 November 25, 2002 November 11, 2002 April 3, 2002 February 25, 2002

September 20, 2004

# COURT CONFIRMS VALIDITY AND ENFORCEABILITY OF PHARMASTEM'S PIONEERING CORD BLOOD PATENTS

Wayne, PA, September 20, 2004 - PharmaStem Therapeutics, Inc. announced today Federal District Court in the District of Delaware confirmed a Jury's previous findings regarding the validity and enforceability of two of its pioneering patents (U.S. Patent 1 5,004,681 and 5,192,553). On October 29, 2003, a Jury in Delaware found that PharmaStem's patents were valid, enforceable and willfully infringed by the defendan ViaCord, CBR (Cord Blood Registry), Cryo-Cell International and Corcell. Nicholas Di CEO of PharmaStem Therapeutics, stated, "I am very pleased that the Court has rule PharmaStem's patents are valid and enforceable. It is gratifying to know that the inno advances made by our scientific founders have been recognized by the Court."

With respect to infringement, the Delaware jury found that 100% of the cord blood un collected and stored by defendants infringed the '681 Patent, because the Jury found 100% of the cord blood units the defendants collected and stored for families had ence stem cells to be therapeutically useful for children and adults. The defendants argued trial that not all of the cord blood units they stored for families contained enough stem for such use. The Court ruled that the evidence "suggests that at least some of the defendants' cord blood units infringe" the '681 Patent, but because of procedural ruling partial retrial was needed to determine the defendants' level of infringement and result damages. "PharmaStem expects to obtain an injunction prohibiting defendants from collecting and storing cord blood units that have enough stem cells to be therapeutical useful for children and adults," said Mr. Didier.

With respect to the '553 Patent, the defendants alleged at trial that they did not infring patent because they did not own the cord blood units, and that only the owner of the (i.e., the families who bank with the defendants) could be liable for such infringement Delaware jury disagreed with the defendants and found that they infringed this patent court, however, apparently agreed with the defendants and set aside the jury's verdic based upon its interpretation of infringement as applied to the '553 Patent. PharmaSt-believes that the court used an improper legal standard and is confident it will prevail appeal and the jury's verdict will be reinstated.

PharmaStem's pioneering patents have been recognized by the vast majority of the pumbilical cord blood industry. At this time, 16 of the 20 private cord blood banks open in the United States have taken a license to PharmaStem's patent portfolio. The only remaining unlicensed banks are the defendants ViaCord, CBR (Cord Blood Registry) Cell International and Corcell. PharmaStem has additional patent lawsuits pending at these unlicensed banks.

Contact: Nicholas Didier

September 22, 2004

TO:

Hans Lee

American College of Obstetricians and Gynecologists

FROM:

Paul Andre

RE:

PharmaStem Cord Blood Patents

#### Who is PharmaStem Therapeutics, Inc. (PharmaStem)?

Biocyte Corporation, the predecessor of PharmaStem, was the pioneer in the development and implementation of cord blood preservation and its therapeutic use and was the first cord blood bank in the world. Umbilical cord and placental blood is rich in stem cells that can reconstitute the human blood and immune systems. PharmaStem provided the roadmap for the creation of today's rapidly growing field of cord blood storage. The freezing ("cryopreservation"), at or shortly after birth, of blood from the infant's umbilical cord and placenta enables the "hematopoietic" (blood producing) stem cells contained in the blood to be thawed at a later time and used for the reconstitution of the blood and the immune systems for the treatment of anemia, leukemia and other blood disorders. Prior to the pioneering work of PharmaStem's scientific founders, cord blood was considered a medical waste product and was discarded at birth. After the scientist at PharmaStem successfully completed in vitro analysis and in vivo animal model studies with cord blood to determine the suitability of using the cord blood stem cells therapeutically, the company performed the first cord blood stem cell transplant in a Fanconi anemia patient in 1988. Since that time, thousands of transplants have been successfully performed in children and adults using cord blood stem cells.

#### What are the PharmaStem patents?

In 1987, following the pre-clinical work with cord blood stem cells and prior to the first successful human transplant, PharmaStem filed patent applications for the therapeutic compositions and therapeutic method of use of cord blood stem cells. There are currently five (5) issued United States patents owned by PharmaStem that cover a range of compositions and activities regarding therapeutic stem cells derived from cord blood. The first two of these patents, the '681 and '553 patents, issued in the early 1990's, with the remaining three patents issuing within the past two years. The '681 patent was reexamined by the United States Patent and Trademark Office (USPTO) after a competing cord blood bank filed such a request on grounds of invalidity. Following reexamination, the USPTO issued a reexamination certificate on April 11, 2000, reaffirming the novel contributions of

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PharmaStem's patent. Recently, another party has requested reexamination of the '681 and '553 patent again, and those reexaminations are currently pending in the USPTO.

#### What is the status of the litigations involving the PharmaStem patents?

The '681 and '553 patents have been asserted by PharmaStem in a lawsuit for patent infringement, filed on February 22, 2002, in the United States District Court for the District of Delaware against ViaCell (ViaCord), Cryo-Cell International, CorCell, and CBR Systems (Cord Blood Registry). On October 29, 2003, a Delaware jury unanimously found that the two PharmaStem's pioneering patents were valid and enforceable and that the four defendants ViaCord, CBR (Cord Blood Registry), Cryo-Cell and Corcell had willfully infringed these patents. Recently, the Court confirmed the Jury's previous findings regarding the validity and enforceability of PharmaStem's two pioneering patents. However, with respect to infringement, the Court ordered a partial re-trial to determine the extent of infringement of the '681 patent, and has set aside the verdict with respect to infringement of the '553 patent.

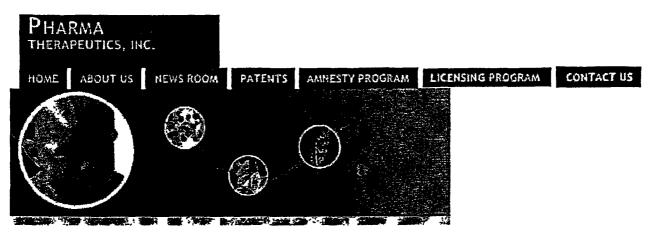
PharmaStem has also initiated patent infringement lawsuits for its recently issued patents in Massachusetts, Pennsylvania, Florida, and two in California. The new lawsuits name the four unlicensed cord blood banks named in the Delaware litigation, and physicians and health care providers who work with these unlicensed cord blood banks.

#### Why are physicians receiving PharmaStem's "Amnesty Agreement"?

So far, PharmaStem has filed patent infringement lawsuits against over two dozen physicians who work with the four unlicensed cord blood banks. PharmaStem does not want to name physicians in its patent infringement lawsuits, or cause a chill effect on the rapidly growing field of private cord blood storage. As such, PharmaStem has developed an "Amnesty Program" that relieves physicians of liability for any past infringing activity and insures that they will not be named in any future litigation by PharmaStem. Pursuant to the agreement, PharmaStem requires that the physicians do not knowingly collect cord blood for unlicensed cord blood banks or promote their services. Instead, PharmaStem encourages physicians to collect for any one of the sixteen (16) licensed cord blood banks. The PharmaStem Amnesty Program has been joined by hundreds of physicians, and another obstetrician and gynecologist society has recommended its members join the Amnesty Program as a precautionary measure against being named as a defendant in a lawsuit.

#### Who can physicians talk to learn more about PharmaStem?

PharmaStem is represented by the national law firm of Perkins Coie LLP with regional offices in the Bay Area. For more information about PharmaStem, its patent portfolio, or the status of the various patent litigations, you may contact Paul Andre, a partner at Perkins Coie, at (650) 838-4370.



#### LICENSED BANKS

California Cryobank Stem Cell Services

New England Cord Blood Bank

Stembanc

**Cord Partners** 

**Cord Blood Family Trust** 

Securacell

Alpha Cord

**Cryobanks International** 

Newborn Blood Banking

LifeBank USA

CORD

**CureSource** 

Norton Hospitals / Family Link

**Hemastem Therapeutics** 

GeneAngel

Lifestor

## **UNLICENSED BANKS**

VIACORD CBR (Cord Blood Registry) CRYO-CELL International CORCELL

On October 29, 2003, a Delaware jury unanimously found that two of PharmaStem's pioneering patents, US Patent Nos. 5,004,681 and 5,192,553 were valid and enforceable and that the four defendants, ViaCord, CBR (Cord Blood Registry) Cryo-Cell and Corcell had willfully infringed these patents.

Home | About Us | News Room | Patents | Amnesty Program | Licensing Program | Contact Us

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Case 1:04-cv-11673-RWZ Document 29-3 Filed 11/16/2004 Page 62 of 65

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News

#### Summer 2004 PAMR Information and recommendations

Information and recommendations generated from the reviews conducted during the fourth quarter of 2003 More...

Thank You! FOGS and the Florida Section ACOG recognize their corporate supporters More...

# Acid Community Outreach Through a successful combination of paid media and local outreach, the

The CDC's Folic

Centers for Disease
Control and
Prevention (CDC)
has significantly
increased awareness
of the importance of
taking folic acid to
reduce the risk of
certain birth defects
in Miami's Hispanic
community.
More...

# Liability Issues Report Please use this form

Please use this form liberally to report the related practice problems you are facing The Form

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# **PharmaStem Amnesty Agreement**

Christopher L. Nuland, Esq. General Counsel

Over the past several weeks many FOGS members may have received a proposed "Amnesty Agreement" from PharmaStem Therapeutics, Inc., urging Ob-Gyns to execute the Agreement in order to "avoid legal action from PharmaStem relating to its patents." In response to inquiries from members, FOGS would like to provide the following background information.

Read Other Legal News PharmaStem Amnesty Agreement Court Rulings Affect Hospitalbased Physicians

PharmaStem indeed does hold several patents for the "isolation and preservation and neonatal hematopoietic stem and progenitor cells of the blood," and it is also true that PharmaStem has vigorously defended its intellectual property rights, having secured a \$7.1 million verdict against several blood banks in November, 2003. The current suits to which the cover letter refers pertain to new PharmStem patents, but involve many of the same laboratories involved in the 2003 suit. Because uniform and vigorous enforcement of intellectual property rights are essential legally to the very maintenance of such rights, PharmaStem is expected to continue its aggressive litigation in this arena.

As part of the latest round of lawsuits, PharmaStem has sent the proposed Amnesty Agreement to many obstetricians suspected of using "unlicensed" cord banks. In this case, the term "unlicensed" does not mean that the named banks have not been appropriately licensed by the state, but rather that they have not executed a licensing agreement with PharmaStem for the use of the latter's patented technology (several of the defendant labs reportedly currently are in negotiations to obtain such licenses).

The Amnesty Agreement actually serves several purposes for PharmaStem. First, it directs obstetricians to use PharmaStem-licensed banks, thereby increasing the company's market share and actually increasing the value of the patents. Second, the Agreement itself allows PharmaStem to disclose the Amnesty Agreement to others, meaning that it likely will be used in litigation as evidence of the defendant's alleged use of the patented technology.

With the above in mind, should FOGS members sign the Agreement and stop using the named blood banks that are in alleged violation of PharmaStem's patent rights? While PharmaStem has alleged that it will defend its property rights against "obstetricians if they continue to work with unlicensed cord blood banks," neither the past nor present lawsuits appear to have named individual physicians as defendants. Moreover, such a suit may only be brought if the physician has "constructive knowledge" that the unlicensed use of patented technology is involved.

However, the cover letter and Agreement itself may serve as such constructive notice, and FOGS members are urged to exercise extreme caution when collecting cord blood for any of the defendant blood banks. Those wishing to insulate themselves from any possible litigation may want to execute the Agreement, although it is recommended that a cover letter be attached in which the obstetrician states that "the execution of the Amnesty Agreement should not be construed as an

admission that the practice has had any relationship with any of the named cord blood banks, nor should the execution of the Agreement be construed as an opinion as to the merits of the referenced litigation." These statements should reduce the likelihood that the physician will be called as a witness in the actual litigation.

FOGS members with further questions are invited to contact the Office of General Counsel directly at <a href="mailto:nulandlaw@aoi.com">nulandlaw@aoi.com</a>.

#### Added September 21, 2004

Last week's information sheet on the PharmaStem Amnesty Agreement appears to have answered many member questions, yet also raised a few additional issues:

**Q:** I heard that PharmaStem's patent infringement victory was overturned. What does that mean to me?:

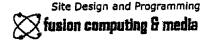
A: The most significant part of the Court's finding for obstetricians (which dismissed one infringement count and called for a new trial on the second) was that infringement could not occur unless a party was involved in all three parts of the patented process, i.e., the isolation of stem cells, the preservation of the cells, and the introduction of the cells into a suitable host. If this finding, a physician will not be held liable for infringement so long as he or she does not participate in the reintroduction of the cells, a process in which few, if any, obstetricians participate.

 $\mathbf{Q}$ : I have not and do not draw cord blood. Do I have to concern myself with the Agreement?

A: No, unless you are actively promoting the use of non-PharmStem-licensed cord blood banks.

Q: You suggest that obstetricians exercise extreme caution when dealing with non-PharmStem cord blood banks. What does "extreme caution" mean?

A: Some suggestions include obtaining indemnifications from the blood bank (which they are usually willing to provide), refusing any remuneration associated with using a particular blood bank, and refraining from marketing a single blood bank. Moreover, as stated above, obstetricians may want to refrain from participating in the reintroduction process.



## **CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on October 15, 2004, I caused a true copy of the foregoing motion to be served upon the following counsel of record:

### **BY FEDERAL EXPRESS**

Paul J. Andre, Esq. Lisa Kobialka, Esq. Perkins Coie LLP 101 Jefferson Drive Menlo Park, CA 94025

Attorneys for Defendant

## BY HAND DELIVERY

Philip A. Rovner, Esq.
Potter Anderson & Corroon LLP
Hercules Plaza
1313 North Market Street
Suite 600
Wilmington, DE 19801

Attorney for Defendant

Pharmastem Therapeutics, Inc. c/o The Corporation Trust Company Corporate Trust Center 1209 Orange Street Wilmington, DE 1980

Alyssa M Schwartz (#4351